Hollingsworth LLP

Robert E. Johnston
dir 202 898 5845
rjohnston@hollingsworthllp.com

January 22, 2010

Honorable Kiyo A. Matsumoto
United States District Court
Eastern District of New York
225 Cadman Plaza East
Brooklyn, New York 11201

Re: In re: Pamidronate Products Liability Litigation; Case No. 1:09-md-2120-KAM-SMG; Case No. 1:09-cv-05288 (*Eckblom*)

Dear Judge Matsumoto:

Defendant Sandoz, Inc. ("Sandoz") respectfully submits this correspondence in accordance with Chambers Practices, Sections IV.B and I .C. Sandoz intends to file a Motion for Judgment on the Pleadings in the above-reference matter, pursuant to Federal Rule of Civil Procedure 12(c), on the grounds that it fails to meet the minimum pleading requirements of Federal Rule of Civil Procedure 8(a) for each of the counts asserted. Plaintiff Suzanne Eckblom alleges counts for strict liability, negligence – negligent manufacture, negligence – failure to warn, breach of express warranty, and breach of implied warranty. Plaintiff Frank Eckblom alleges a count for loss of consortium. Foremost among plaintiffs' pleading deficiencies is their failure to allege that their injuries were caused by generic pamidronate sold, marketed, or distributed by Sandoz or that Mrs. Eckblom was treated with a Sandoz product.

In accordance with Chambers Practices, Sections IV.B and IV.C, Sandoz proposes to serve its Motion for Judgment on the Pleadings as soon as permitted by the Court. Sandoz proposes that any opposition be due fourteen (14) days following Sandoz's service of its motion, with Sandoz's reply due seven (7) days following the service of any opposition. A summary of the grounds for Sandoz's motion is set forth below.

Plaintiffs identify Novartis Pharmaceuticals Corporation as the company "engaged in the business of marketing, distributing, promoting, testing, labeling and selling the drugs Aredia® and Zometa®." Complaint ¶ 5. With respect to generic pamidronate, plaintiffs allege that APP Pharmaceuticals Corporation, Bedford Laboratories, Hospira, Inc., Teva Parenteral Medicines, Inc., Aesgen, Inc., Akorn, Inc., Cipla Ltd., and Sandoz, Inc. were "engaged in the business of marketing, distributing, promoting, testing, labeling and selling generic Aredia (pamidronate)."

See id. ¶¶ 7, 9, 11, 13, 15, 17, 19, 21.[1] Plaintiffs further allege that Mrs. Eckblom "was prescribed, purchased, and was infused with Aredia® and/or generic Aredia (pamidronate) and as a result thereof suffered severe osteonecrosis of the jaw." *Id.* ¶ 2. Notably, plaintiffs do not allege that Sandoz sold, marketed, or distributed pamidronate that Mrs. Eckblom actually used. Of course, if Mrs. Eckblom never used pamidronate from Sandoz, then Sandoz cannot have caused her alleged injuries and all claims against Sandoz must be dismissed.

Federal pleading standards mandate that a plaintiff plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *Arar v. Ashcroft*, 585 F.3d 559, 569 (2d Cir. 2009). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009); *see also Willets Point Indus. and Realty Ass'n v. City of New York*, No. 08-cv-1453, 2009 WL 4282017, at * 3 (E.D.N.Y. Nov. 25, 2009). Here, plaintiffs' Complaint fails as a matter of law because it fails to allege that Sandoz's product was the cause of their alleged injuries. As will be more fully discussed in Sandoz's brief, to prevail on any of their claims under California law, plaintiffs generally must identify the specific defendant responsible for an actionable harm. *See, e.g., Sindell v. Abbott Labs.*, 607 P.2d 924, 928 (Cal. 1980) (recognizing that "as a general rule, the imposition of liability depends upon a showing by the plaintiff that his or her injuries were caused by . . . the defendant"). In addition, plaintiffs' must identify a manufacturer for their warranty claims. *See Brown v. Superior Court*, 751 P.2d 470, 484 (Cal. 1988) (declining to extend market share liability theory to warranty claims).

Based on these principles and federal pleading standards, Sandoz will argue that the Complaint fails to state a claim upon which relief may be granted because plaintiffs have not identified Sandoz as the seller, marketer, or distributor of any pamidronate that Mrs. Eckblom took. *See Arar*, 585 F.3d at 569 (dismissing complaint where plaintiff "fail[ed] to specify any culpable action taken by any single defendant"). Plaintiffs merely present the possibility that Sandoz, as one of many sellers of pamidronate, could have been the seller of pamidronate that Mrs. Eckblom took. Factual allegations "must be enough to raise a right to relief above the speculative level." *Arar*, 585 F.3d at 569 (quoting *Twombly*, 550 U.S. at 555). It is not enough that "the pleadings [leave] open the possibility that a plaintiff might later establish some set of undisclosed facts to support recovery." *Twombly*, 550 U.S. at 561 (internal quotations omitted). "Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief" and must be dismissed. *Iqbal*, 129 S. Ct. at 1949 (quotations omitted); *Willets Point Indus.*, 2009 WL 4282017 at * 3. Because plaintiffs' pleaded facts "do not permit the court to infer more than the mere possibility of misconduct," the Complaint "has not shown that the pleader is entitled to relief," and must be dismissed. *Iqbal*, 129 S. Ct. at 1950 (quotations omitted); *Capela v. J G. Wentworth, LLC*, No. CV09-882, 2009 WL 3128003, at * 3 (E.D.N.Y. Sep. 24, 2009).

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[1] While this case was pending in the District Court for the District of Columbia, the court *sua sponte* dismissed without prejudice Teva Parenteral Medicines for failure to timely serve the Complaint.

Plaintiffs cannot rely on the discovery process to determine the manufacturers of the products at issue. The Rule 8(a) pleading requirement is designed to protect defendants against the significant costs of defending against vague or unfounded allegations. Specifically, the Supreme Court rejected the notion that "a claim just shy of a plausible entitlement to relief can, if groundless, be weeded out early in the discovery process through 'careful case management.'" *Twombly*, 550 U.S. at 559. Here, plaintiffs' vague allegations preclude Sandoz from showing that it could not have supplied the pamidronate that Mrs. Eckblom took. Plaintiffs indicate neither when Mrs. Eckblom received generic pamidronate infusions nor where she received those infusions. With regard to Sandoz's conduct, plaintiffs allege that "[a]t all times relevant hereto, Sandoz was engaged in the business of marketing, distributing, promoting, testing, labeling and selling generic Aredia (pamidronate)." Complaint ¶ 21. In fact, Sandoz did not sell pamidronate before 10/5/2005 and stopped selling pamidronate on either 6/16/2008 or 7/10/2008, depending on the formulation. Moreover, Sandoz's market share never exceeded 2%. These circumstances present a a low likelihood that Mrs. Eckblom's pamidronate came from Sandoz. Sandoz should not be required to proceed through potentially expensive and unnecessary discovery based merely on plaintiffs' conclusory allegations. Plaintiffs must allege facts showing something "beyond the mere possibility of [relief], lest a plaintiff with a largely groundless claim be allowed to take up the time of a number of other people, with the right to do so representing an in terrorem increment of the settlement value." *Twombly*, 550 U.S. at 546 (quotations omitted).

Sandoz will also argue in its Motion for Judgment on the Pleadings that plaintiffs' counts fail to plead factual allegations to support their California state law claims for strict liability, failure to warn, negligence, breach of warranties, and loss of consortium. In addition to plaintiffs' failure to allege causation sufficiently (due to the overarching product identification issue), plaintiffs' counts amount to nothing more than "a formulaic recitation of the elements of a cause of action," which "will not do." *Twombly,* 550 U.S. at 555; *see also Iqbal*, 129 S. Ct. at 1949 ("Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice."). For example, plaintiffs' conclude that the defendants did not adequately warn Mrs. Eckblom, but they do not give any information about what warning was given or what warning was omitted. Plaintiffs conclude that defendants failed to adequately test their products, but they do not give any information about what tests were conducted or what tests should have been conducted. Plaintiffs' complaint is replete with such unsupported legal conclusions, which *Iqbal* makes clear are not worthy of the presumption of veracity, and are insufficient to demonstrate a plausible entitlement to relief. *See Iqbal*, 127 S. Ct. at 1951.

Respectfully yours,

Robert E. Johnston

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on the 22nd day of January, a copy of the foregoing correspondence was filed electronically. Notice of the filing will be sent to the parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

Dated: January 22, 2010 By: /s/ Robert E. Johnston